

1 IN THE UNITED STATES DISTRICT COURT  
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
2 AT CHARLESTON

3 TRANSCRIPT OF PROCEEDINGS

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6 :  
7 IN RE: DIGITEK PRODUCT : CIVIL ACTION  
7 LIABILITY LITIGATION : NO. 2:08-MD-01968  
8 :  
8 : April 13, 2010  
9 -----x

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11 MOTIONS HEARING

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13 BEFORE THE HONORABLE MARY E. STANLEY  
13 UNITED STATES MAGISTRATE JUDGE

14

15 APPEARANCES:

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1 APPEARANCES (Continued) :

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20 Court Reporter: Lisa A. Cook, RPR-RMR-CRR-FCRR

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22 Proceedings recorded by mechanical stenography; transcript  
produced by computer.

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# 1 PROCEEDINGS

2 THE COURT: Good morning.

3           This is the *Digitek Product Liability Litigation*, MDL  
4   Number 1968. And I'm going to make sure that everybody can  
5   hear each other.

6 First, let's start with the plaintiffs. Remember, we  
7 don't have a court reporter here. Speak into the microphone  
8 because it's through the microphone that the folks on the  
9 phone, telephone will hear you. And if counsel wish to  
10 remain seated, they may.

11 Mr. Thompson.

12 MR. THOMPSON: Yes, Your Honor. Should we simply  
13 introduce ourselves for the record?

14 THE COURT: Yes, please.

15 MR. THOMPSON: My name is Fred Thompson. I'm an  
16 attorney with Motley Rice. I'm appearing on behalf of the  
17 Plaintiffs' Steering Committee.

18 MS. CARTER: Meghan Carter from Motley Rice on  
19 behalf of the plaintiffs.

20 MR. FRANKOVITCH: Carl Frankovitch on behalf of  
21 the plaintiffs.

22 MR. MILLER: Pete Miller from the Miller Firm on  
23 behalf of the plaintiffs.

24 THE COURT: If you'd like to pull up to the table,  
25 go ahead, Mr. Miller.

1           And for the defense?

2           MR. MORIARTY: Your Honor, I'm Matt Moriarty here  
3         from Tucker, Ellis & West on behalf of the Actavis  
4         defendants.

5           MS. BETTS: And Rebecca Betts of Allen, Guthrie &  
6         Thomas on behalf of the defendants.

7           THE COURT: And did the folks on the telephone  
8         hear all of those introductions?

9           MR. ANDERTON: It's very difficult, Your Honor.

10          THE COURT: Did you hear any of them?

11          MR. ANDERTON: Yes, we were able to hear them, but  
12         very faintly.

13          THE COURT: Okay. If you would introduce  
14         yourselves, please.

15          MR. ANDERTON: Michael Anderton with Tucker, Ellis  
16         & West on behalf of the Actavis defendants.

17          MS. DOWNIE: And this is Erika Downie from Shook,  
18         Hardy & Bacon on behalf of the Mylan defendants.

19          THE COURT: All right.

20          Well, I will ask counsel to remain seated to be sure  
21         that you speak directly into the microphone. Court  
22         reporters are in very short supply in this district. We  
23         have a death penalty case going on, and we've got the Pagan  
24         motorcycle case about to start and there's just too many  
25         hearings.

1           It may be that if you insist on court reporters that  
2 you'll need to just make your own arrangements. I don't  
3 know. We'll have to consult with the clerk on that. But in  
4 the meantime, this will be digitally recorded. And then if  
5 a court reporter can find the time to produce a transcript,  
6 they will if you want one.

7           All right. We are here on the plaintiffs' motion to  
8 compel deposition testimony. I have reviewed your, your  
9 memoranda carefully.

10          Is it going to be your case, Mr. Thompson, your motion?

11           MR. THOMPSON: Yes, Your Honor, I'll be the  
12 speaking part for the plaintiffs. And only if I am overcome  
13 will there be another speaker. So, I will speak on behalf  
14 of the plaintiffs.

15           THE COURT: All right.

16          First, I need you to bring me up-to-date as to what you  
17 have learned, if anything, with respect to the discovery of  
18 the products that were manufactured preceding each batch of  
19 Digitek. I have never received any feedback as to whether  
20 there were a limited number of products or a broader number,  
21 whether there were, there was really anything of note that  
22 came forward from that --

23           MR. THOMPSON: Your Honor, --

24           THE COURT: -- discovery.

25           MR. THOMPSON: -- let me speak to this, and I will

1 be subject to being poked in the side if I misstate this.

2 My understanding is that the defendants have complied  
3 with PTO 27 and 37 in supplying the batch record for the  
4 batch that, that preceded and followed the Digitek batch on  
5 the, that was the recalled batch. I think that we have that  
6 information. And, so, that's there for us to examine.

7 As far as anything of note, the, the documents -- we  
8 have not seen anything that, that's remarkable to us. But  
9 the defendants, I believe, have complied with your order to  
10 send those, the batch records. I don't know if you are  
11 inviting me now to, to commence to further argument.

12 THE COURT: No, I've got a couple of other  
13 questions.

14 What I'm wondering is whether there is a particular  
15 product, like I think phentermine or aspirin or some antacid  
16 or something that was typically the preceding product or  
17 succeeding product.

18 MR. THOMPSON: Judge, I don't know the answer to  
19 that. That has been the subject of, of two responses  
20 generally in our questioning. One is there will be an  
21 objection that information regarding specific drug or  
22 product lines other than Digitek are forbidden by PTO 27 and  
23 the witness is directed not to answer. That's the first  
24 source of frustration for us.

25 The second is more generic, and that is there is a

1 tremendous amount of, "I don't know, I don't recall." We're  
2 not seeking relief on that. I think that's just part of the  
3 landscape, that people's memories don't seem to be so great.

4 But with regard to the production of other products, we  
5 have been foreclosed from going down those paths in  
6 inquiring about the, the, the, the use of the, the  
7 personnel, the quality assurance systems, the quality  
8 control systems, and the production at the plant.

9 I think that we have become more sophisticated in our  
10 understanding of the plant, and that is that the batch  
11 records by and large are -- while they're, they're certainly  
12 helpful, they're not, they're not the central focus of our  
13 general good manufacturing processes inquiry.

14 What we are much more interested in are the systems and  
15 the training and the production and the quality assurance  
16 areas which do cross product lines and which are generally  
17 applicable to the plant operations.

18 And to the extent that, that, that we are asking  
19 questions that relate to that good manufacturing processes,  
20 we believe that the, that the, the, the, the -- and I'm  
21 going to describe it as overly ambitious interpretation of  
22 PTO 27 by the defendants is misplaced.

23 I think that, that, that, that the use of these  
24 objections and specific limitations solely to Digitek  
25 actually creates not just incomplete answers, but it creates

1 incorrect answers.

2 For example, one of our examples that we put up was  
3 Mr. Zhu, Z-h-u. I asked him did he know why the plant  
4 closed. He said, "Yes." Apparently there was an  
5 announcement. And I said, "What did they tell you?" And  
6 they objected, directed the witness to answer only as to  
7 Digitek.

8 Now, certainly the answer to the question, "What did  
9 they tell you about why the plant closed," certainly to the  
10 extent that it included Digitek, that's part of the answer.  
11 But to the extent that it included anything else -- if, for  
12 example, they simply said, "Well, our business plan was to  
13 close the plant," whatever that answer is, it's relevant if,  
14 if it elicits information that is going to be eventually  
15 inadmissible at trial.

16 Certainly, all of the safeguards of trial will be in  
17 place. All of the safeguards of the protective order are in  
18 place. And it's simply overly aggressive to use the PTO 27  
19 as a grounds to direct witnesses not to answer questions  
20 with regard to the general plant operation, with regard to  
21 production quality, quality control.

22 That's -- and here I don't want to simply restate what  
23 we have written in our, our memorandum because I know you've  
24 studied it very carefully and you don't need to hear me  
25 reiterate. But that's, that's the gravamen of our position

1 is that as we enter the final 60 days of this factual  
2 discovery period, we're going to be taking the second day of  
3 Mr. Dowling. I believe we've got a second day of  
4 Mr. Bitler. We're going to be taking the president of the  
5 corporation. We're going to be taking various production  
6 managers.

7 And we need to use this time productively to get the  
8 information with regard to current good manufacturing  
9 practice as it existed at the plant so that our experts can  
10 be ready to give their reports on June the 5th and June the  
11 15th. And, so, that's why I brought this before you now.

12 We, in fact -- as we have briefed, we, in fact, believe  
13 that PTO 27, which was exhaustive in its analysis, was, in  
14 fact, an order that was based upon a certain understanding,  
15 or a certain, I think, lack of understanding of how that  
16 plant operated and how Digitek was produced.

17 And we believe that we have now come back before you  
18 with additional information that shows that Digitek, far  
19 from being a unique and stand-alone process, was, in fact,  
20 part of a common process in which the systems and in which  
21 the production crossed lines.

22 So, those are the -- I realize that I was supposed to  
23 be answering a specific question, and I think I've now  
24 argued my opening case.

25 THE COURT: Well, let me ask this. Has

1       Mr. Galea's deposition been taken again?

2           MR. THOMPSON: He has been taken once. Oh, we, we  
3       did take his second deposition, or we reopened it based on  
4       the critical analysis --

5           THE COURT: Order.

6           MR. THOMPSON: Yes, Your Honor.

7           THE COURT: And was he instructed not to answer  
8       during that deposition?

9           MS. CARTER: Your Honor, --

10          THE COURT: You need to get next to a mike, Ms.  
11       Carter.

12          MS. CARTER: Your Honor, the deposition was very  
13       short, and I don't believe that he was instructed not to  
14       answer questions about his assessment. But the scope of the  
15       deposition was limited to just the assessment and not  
16       necessarily to other documents. I believe there was an  
17       objection concerning other documents introduced, but it went  
18       on accordingly.

19          MR. THOMPSON: Judge, --

20          THE COURT: Yes, Mr. Thompson.

21          MR. THOMPSON: Judge, I do believe that your  
22       thought process in PTO 52 in considering Mr. Galea's, that  
23       assessment and critical privilege analysis, I believe that  
24       PTO 52 in essence recognizes that, that, that, that the  
25       information doesn't have to be stamped Digitek in order to

1     be relevant, probative, and discoverable with regard to the  
2     cGMP. And I believe that we, that that thought process in  
3     PTO 52 should be part of our process as we go forward with  
4     these additional two months of factual depositions.

5                 THE COURT: Are the plaintiffs going to pursue  
6     recovering attorneys' fees with respect to PTO 52?

7                 MR. THOMPSON: Your Honor, the answer to that is  
8     that Mr. Moriarty and I have determined not to, to, to file  
9     a, a, a -- we are not. And I don't know if that -- I don't  
10    know if you like that or don't like that, but we are not  
11    going to pursue the fees for that. We believe that it was  
12    a -- well, we're not going to pursue it.

13                 THE COURT: Okay. That's the answer.

14                 Was there anything further that -- well, how many of  
15    the quality department people, quality assurance, quality --  
16    there's several aspects of quality control and assurance --  
17    have, depositions have you taken? How many of those folks?

18                 MR. THOMPSON: Judge, Your Honor, we've taken, I  
19    believe, 24. Our best estimate is approximately half of  
20    those have been devoted to quality people.

21                 THE COURT: And is it fair to say that with  
22    respect to all of those people that they were instructed not  
23    to answer except as to Digitek?

24                 MR. THOMPSON: Your Honor, I believe that in every  
25    deposition there has been a question that has been responded

1 to by an objection and direction not to answer. In some  
2 it's been more prevalent than in others.

3 And if that was a, that was a key determinative to the  
4 Court, I would want to give you a grid or give you an  
5 exhaustive listing of that, which I have not done. But  
6 that's the -- I believe that it's correct to say that in  
7 every deposition there have been at least one assertion of,  
8 of that direction not to answer.

9 THE COURT: Thank you.

10 Was there anything further that you wished to bring to  
11 the Court's attention today or at this point in the hearing?

12 MR. THOMPSON: Judge, at the commencement of our  
13 reply memorandum, I included an executive sort of a summary  
14 statement. And I want to tell the Court that that was  
15 written in the heat of the night. Tempers were, were  
16 raging. And I believe that upon several days of reflection  
17 that I would have removed several of those adjectives. And  
18 I apologize for that.

19 THE COURT: Well, sometimes reading memos gets  
20 really boring, and this one woke me up a little bit. So, I  
21 thought it was perhaps a little overstated, but not  
22 offensively so. And, besides, it's nice to see that  
23 somebody has a good use of vocabulary.

24 Mr. Moriarty, Ms. Betts.

25 MR. MORIARTY: Despite his excellent use of

1 vocabulary, we were offended. I'll get to that later.

2 Let me address two of the questions that you had to Mr.  
3 Thompson.

4 One is my memory of what happened in the wake of that  
5 ruling on PTO 27 is that we offered to provide all those  
6 batches. We went back. We identified them. And we said,  
7 "PSC, we've identified X number of batches that fall into  
8 this category. Do you want them?" And they never asked for  
9 them. That's my memory of it.

10 Second, in your second question to Mr. Thompson, he  
11 said something very interesting to me. And that is that  
12 they've gone through all these Digitek batch records, but he  
13 clearly reflected that there's, you know, nothing in them.  
14 They don't really care about them. And that is very telling  
15 about this litigation in general and why we are here today.  
16 Okay?

17 So, under 30(c)(2) we have a right to assert objections  
18 when we are trying to enforce court orders. So, let's talk  
19 about court orders and motions to compel.

20 The way the defense reads Rule 37(a)(3)(B)(i), which is  
21 what they have moved on, is that you have to be addressing a  
22 question or perhaps even a witness.

23 What they're really addressing here in this supposed  
24 motion to compel is really very vague for us to address  
25 because it is not a question. It's not a witness. It's

1 thousands of pages of testimony and dozens of witnesses  
2 retrospectively and prospectively, which makes it very  
3 difficult for us to hone in and say exactly what should be  
4 going on here. And it's very difficult to enforce going  
5 forward even if there could be such an order.

6 But what is the court order that we are really focused  
7 on? And I think it's PTO 27. And I went back and I read  
8 all the briefs and PTO 27 itself.

9 And if you look at the first page of their brief that  
10 we're here about today, it's very clear about what they  
11 want. They want to talk about all pharmaceuticals, all  
12 other drugs. They want a second bite at the apple.

13 If you go back to the initial briefing that they did  
14 regarding PTO 27, very early in the brief they are showing  
15 that the true takeoff point here is PTO 12. PTO 27 arose  
16 from a challenge to the scope of PTO 12.

17 As I read all those briefs, it was just remarkable to  
18 me how we are here on almost the exact same issue because  
19 they had already publicly proclaimed by June of 2009 an  
20 abandonment of the double thick theory, which is an  
21 incredibly significant fact because when they abandoned the  
22 double thick theory, as they have repeatedly said in their  
23 briefs over and over, it's a red herring, they're getting  
24 away from the recall.

25 And this recall was not about current good

1 manufacturing practice violations. It's very clear from the  
2 FDA approved recall notices and all the other exhibits that  
3 this was about double thick tablets. It's a very different  
4 and a very, very narrow scoped issue.

5 So, when I looked back at pages 12 through 14 of my  
6 copy of PTO 27 where you are sort of restating the positions  
7 of the parties, it, it, it sinks home very much to what  
8 we're talking about today.

9 And at page 15 you said at that time that whatever they  
10 were arguing about -- and they were arguing about current  
11 good manufacturing principles. It's all through their  
12 briefs at that time. And at that time, the ruling was that  
13 it was, their arguments were too speculative to warrant the  
14 relief that they were seeking. And the same is true today.

15 Why are we here? I expect, Your Honor, that if they  
16 were finding evidence of defective Digitek, which is what  
17 this case is supposed to be about, if they were finding it  
18 in testing of the product that they have, if they were  
19 finding it in our documents, or if they were finding it in  
20 the testimony of our witnesses, we wouldn't be here.

21 We are here because they need a bigger pond to fish in.  
22 They want to cast an ever wider net because the Digitek  
23 batch records, for example, aren't good enough for them.

24 The absurdity of their position is something very  
25 subtle that is buried in their briefs. And the Court's

1 radar ought to go up every time they talk about it, the word  
2 "Riverview". Riverview was a new facility that Actavis was  
3 trying to get on line. It was not FDA approved for  
4 commercial production. Not one single Digitek batch ever  
5 left that plant to go to Mylan or a pharmacy or a consumer.

6 And they want to talk about Riverview all the time  
7 because it's a separate, current, general, good  
8 manufacturing practice issue. It has nothing to do with  
9 Digitek recalled batches or the commercial production of  
10 Digitek or a single tablet in the hands of their clients.  
11 It's a distraction.

12 This issue about -- so, we believe firmly that this is,  
13 this isn't really a motion to compel. If it is, it's so  
14 unfocused that it's very difficult to deal with.

15 We welcome Mr. Thompson producing a grid because we've  
16 tried to put in a number of transcripts as appendices to the  
17 record for this hearing, and if you go through there, you  
18 can see a number of instances admittedly where we asked the  
19 witness to restrict their answer to Digitek, but there are  
20 dozens and dozens and dozens of times where we allow the  
21 witness to answer about good manufacturing practice issues  
22 overall.

23 It's when they start trying to lead the question into  
24 other products specifically. And it's very important to  
25 recognize the distinction between those classifications of

1      questions because sometimes they ask them right and  
2      sometimes they don't.

3           Finally, this issue about Mr. Dowling's affidavit;  
4      false, misleading, misdirecting, fabricated, specious, and  
5      evasive all in one paragraph.

6           Again, I looked at Mr. Dowling's affidavit. I looked  
7      at the briefing for PTO 27. And I looked at Your Honor's  
8      opinion in PTO 27. And back then, people realized that  
9      Mr. Dowling's affidavit was long, many pages.

10          I didn't particularly notice Your Honor's decision  
11      focusing on an issue of whether dye and a lower punch was  
12      the critical issue that turned anybody's opinion.  
13          Mr. Dowling's affidavit had to do with dozens of layers of  
14      things that made Digitek a distinct product from the rooms  
15      in which it was made, the presses on which it was made, the  
16      sequencing, the blending, and everything else.

17          They want to interpret this whole punch and dye issue  
18      as some misdirection. But we've laid out the question and  
19      answer sequence which clearly violated PTO 22 because they  
20      badgered him with the same question over and over to try to  
21      get him to change his answer, and he never did.

22          I have Digitek. Unfortunately, I left it in my car. I  
23      can go get it if I have to. Clearly, the upper punch is  
24      distinct because the stamping on every tablet made in that  
25      plant and sent out has distinct markings on it.

1        This issue in PTO 27 did not turn on whether the dye or  
2    the lower punch were used for one product or two products or  
3    three products. It's still a unique system because you have  
4    to assemble the press in such a way that it works for  
5    Digitek.

6           So, Your Honor, we don't think that some misleading,  
7    specious affidavit or the testimony about that affidavit  
8    warrants a complete overhaul of PTO 27 and a move to open up  
9    discovery to good manufacturing practice issues as to other  
10   products that are not pertinent to a manufacturing defect  
11   case involving one product. That's Digitek.

12           THE COURT: Well, --

13           Mr. Thompson, I'll give you an opportunity to respond  
14   in a little while.

15           I have reviewed all of this material and I remember  
16   very clearly the care I took in writing PTO 27. I relied on  
17   Mr. Dowling's affidavit. And, frankly, I believe I was  
18   misled.

19           I know that the dye that hits the top of the tablet is  
20   unique because it has to be. But I certainly believed that  
21   the other components that punched out the tablet and  
22   compressed it were unique, and it clearly was not.

23           In re-reading Mr. Dowling's affidavit with hindsight  
24   with some of the, in light of the e-mail, reading his  
25   deposition testimony, I believe that PTO 27 would have been

1 different if all of the facts had come out at that point.

2 Now, it sounds to me -- you know, I was hoping that,  
3 that there was a limited number of products that were made  
4 in that room using those blenders, and now we know using  
5 that particular upper and lower punch and the dye or  
6 whatever.

7 And, frankly, I found the limitation on instructions  
8 not to answer except with respect to Digitek to be a  
9 violation of PTO 27 because I opened up discovery to other  
10 products, to a limited number of other products. I didn't  
11 know how many at that time.

12 But I have not heard any evidence or argument from the  
13 plaintiffs that there were a set number of products that  
14 were made with this equipment and that -- so that the  
15 witness could have been asked to talk about current good  
16 manufacturing practices with respect to these blenders, this  
17 room, these punches, whatever.

18 So, I believe that the defense has been overly  
19 aggressive in instructing witnesses not to answer and that  
20 this has thwarted the plaintiffs' ability to investigate  
21 whether, in fact, current good manufacturing practices were  
22 used at the plant with respect to Digitek and reasonably  
23 related products.

24 I'm not happy about this. I think in PTO 52 I made it  
25 clear that the defense was being too aggressive in their

1 limitation. In fact, the entire basis for that motion the  
2 Court found to be not substantially justified and, in fact,  
3 not supported by any cases in the Fourth Circuit.

4 So, the question becomes: Where do we go from here?

5 The -- I'm inclined to suggest that it is an utter waste of  
6 time and money to be looking at batch records and similar  
7 things. The plaintiffs have shown a less than avid interest  
8 in such matters. But they are justifiably interested in  
9 Mr. Galea's testimony, in the quality assurance testimony.

10 As I said at the end of PTO 52, if you would bring  
11 these issues forward sooner, we could save time and we could  
12 save money, and we wouldn't be required to go back and redo  
13 things. But you-all are the lawyers. I'm just expressing  
14 my opinions and making rulings.

15 I am -- it is just such an utter waste of time when  
16 issues come up to instruct a witness not to answer. And for  
17 this now to have extended to 10 or 12 witnesses is  
18 dismaying.

19 I will grant the plaintiffs' motion to compel  
20 deposition testimony, even though it is really not possible  
21 for me to be able to direct my attention to individual and  
22 particular questions. And, in fact, this would appear to be  
23 because the defense has been so aggressive in their  
24 instructions not to answer.

25 Now, I -- the double thick tablets have been off the

1 table for a very long time. The FDA letters, the lack of  
2 good logging of some records, the questionable housekeeping  
3 practices, and the questionable testing of various products  
4 led not just to a recall, but to a total shutdown of the  
5 plant.

6 So, in PTO 52 I wrote that Actavis Totowa's good  
7 manufacturing practices around the time of the FDA's warning  
8 letters and ultimate recall is highly relevant. And the  
9 status of this case now with just two months left convinces  
10 me that the plaintiff should have the opportunity to more  
11 thoroughly inquire with respect to the good manufacturing  
12 practices at those plants during the period in question.

13 Now, I would like some suggestions from counsel as to  
14 how to accomplish this efficiently, economically, and within  
15 boundaries that both sides understand, agree with, and are  
16 willing to enforce.

17 For example, Mr. Thompson, if half of the products are  
18 made as liquids, can we forget them?

19 MR. THOMPSON: Judge, if the question requires a  
20 "yes" or "no" answer, the answer is "no" with an  
21 explanation.

22 To the extent that training personnel in the quality  
23 processes, quality control, quality assurance processes were  
24 plant wide uniformly, I believe that a process even in a  
25 liquid or a gelcap that showed a lack of training or a lack

1    of cleaning or a lack of maintenance, I think that would  
2    have some degree of relevance. I think that would be a  
3    low -- it would be a low tidbit of, of information not very  
4    probative. But I do think that would, that would be  
5    discoverable.

6           To the extent that we're talking about solid pill dose,  
7    solid dosage pills, then we're much closer to the sweet  
8    spot.

9           What I'm most interested in, Your Honor, is if we look  
10   to the various inspections, the various 483s, and the  
11   various responses by Actavis to the FDA findings of defect  
12   and problems that were described by the FDA as a, quote,  
13   total breakdown or a total failure of the system, I'm much  
14   more interested in looking directed to those subject areas.

15           If there are 80 solid pills that are speckled and they  
16   weren't picked up by any quality assurance or any production  
17   people, I believe that's relevant and, and should be, I  
18   should be allowed to inquire into it and to discover it.

19           We're, we're really -- and I agree with you. We're  
20   really not talking about taking a flight from reality and  
21   forming a wish list. What we're talking about is meeting  
22   the Court's deadlines of June the 5th, June the 15th,  
23   October the 13th and 14th for dispositive motions. We're  
24   talking about meeting those deadlines.

25           The first thing that I would like to have is the

1 assurance as we take the now scheduled depositions that we  
2 will have a full and fair opportunity to inquire into these  
3 cGMP areas. That's the first step.

4 The second step would be, I would ask the Court to  
5 allow me to review these depositions. And I know as I'm  
6 sitting here that it will not be more than six or eight that  
7 we would say these folks have knowledge in a certain subject  
8 area that we believe we were foreclosed from going into.  
9 And for a targeted response, we would like an opportunity to  
10 question that person on those areas. And I think that that  
11 would be a good way of, of addressing the testimonial side  
12 of it.

13 The other part is there, there's a, there's another  
14 aspect of this, and I know that this is going to -- I know  
15 that you're going to respond that I, why didn't I say this  
16 earlier. And I want you to understand that much of the  
17 documentary production in this case came during the final  
18 two weeks of December, a large push right at the tail end of  
19 the documentary period.

20 The original date was supposed to be September and that  
21 date was extended until the end of December. And most of  
22 the documents were actually pushed at the end of that  
23 period. There's a large number of redactions.

24 One of the things that you asked was, you know,  
25 Mr. Dowling's affidavit referred to 14 products being

1 produced. And you said, "Well, why haven't you come to me  
2 with more information about that?"

3 Well, when you get the information, everything's  
4 redacted except for one line that says "Digitek" on it.  
5 And, so, we have a brooding redaction problem as well with  
6 regard to the documents on these other cGMP issues as well.

7 And that -- we, we did not make that part of our motion  
8 today, but that is a, a, a brooding problem that we're going  
9 to have to be addressing over time.

10 I don't suggest putting off any of these depositions to  
11 address that, but, but that is sources of information that  
12 have also been withheld under the same thought process.

13 But to specifically address what I think we ought to do  
14 now, I think we ought to have the assurance that we're able  
15 to -- Judge, could I ask for about a one-minute consultation  
16 with my co-counsel?

17 THE COURT: You can have as much time as you want.  
18 Do you want a recess, you know, where I go off the bench, or  
19 you just want to talk among yourselves?

20 MR. THOMPSON: Two, two, two seconds.

21 THE COURT: Go ahead. Talk all you want.

22 (Pause)

23 THE COURT: All right. Have you had enough time,  
24 Mr. Thompson?

25 MR. THOMPSON: Yes, Your Honor. I just wanted to

1 make sure that I was not getting out in front of what my  
2 cooler heads thought. And, and, and we actually are in  
3 agreement that the opportunity to look at the depositions  
4 that have been taken, to select a very limited number, and  
5 to take additional testimony on, on those and to go forward  
6 with the ones that we have scheduled, I think that's the way  
7 that we address it.

8 THE COURT: Well, now, are you -- Mr. Moriarty has  
9 brought up this issue of this Riverview plant. What's your  
10 basis for saying that anything at the Riverview plant is  
11 relevant to this case if no Digitek was ever made there?

12 MR. THOMPSON: Your Honor, it's my  
13 understanding -- I think I'm right on this -- is that the  
14 quality department moved to Riverview in 2007. And, in  
15 fact, many of the quality functions were operated for the  
16 Little Falls plant at the Riverview facility.

17 THE COURT: Well, I mean, it doesn't really matter  
18 where the quality assurance people are located. What  
19 matters is whether they're doing their job with respect to  
20 the plant where the Digitek was made.

21 MR. THOMPSON: Right, right. So, I -- you know,  
22 to the extent I -- I don't think they ever made any Digitek  
23 at Riverview.

24 THE COURT: Right.

25 MR. THOMPSON: They were -- they had invited --

1                   THE COURT: That's what Mr. Moriarty says.

2                   MR. THOMPSON: The, the -- as I say, the personnel  
3       in the quality department, the SOPs, the review, I think the  
4       lab all were at the Riverview facility. And our interest is  
5       in whoever was doing the work for the, for the, for the  
6       Little Falls plant, wherever they might be, Iceland or who  
7       knows where. But, but that's the interest in Riverview.

8                   Now, to the extent that -- and here again, this is now  
9       dredging up old, old memories. But the original reason for  
10      the FDA inspectors to come in 2008, I believe, was as an  
11      initial inspection to shift operations and to commence new  
12      lines at the Riverview plant.

13                  THE COURT: Are you speaking of the first FDA  
14      letter in 2006?

15                  MR. THOMPSON: No, no, Your Honor. I'm talking  
16      about in 2008.

17                  Judge, what I'm hearing is that they did press tablets,  
18       they did produce Digitek at Riverview, but it was not  
19       commercially released. It did not enter into the stream of  
20       commerce. That's my -- that's what I'm being told.

21                  THE COURT: All right. Well, the two FDA letters  
22      that have been reviewed in this case are from 2006 and 2007  
23      with the recall occurring in the spring of 2008. Right?

24                  MR. THOMPSON: Right.

25                  THE COURT: Right, okay. So, I got confused when

1 you talked to me about an FDA inspection in 2008.

2 MR. THOMPSON: Oh, yes, Your Honor. There was an  
3 inspection at, that inspected in, I believe it was March  
4 through May of 2008.

5 THE COURT: At the -- when the recall occurred and  
6 when the plant was shut down.

7 MR. THOMPSON: Yes, Your Honor.

8 THE COURT: Okay.

9 MR. THOMPSON: And there were a series of  
10 observations in that 483 that talked about quality, talked  
11 about various problems that they had ascertained. And they  
12 talked about those problems as examples of plant problems  
13 that they saw.

14 THE COURT: But I believe we've, "we" meaning  
15 judicial officers, have never seen that letter.

16 MR. THOMPSON: This, this was the 483, Your Honor.  
17 Now, I would --

18 THE COURT: And, so, you know, -- we've only seen  
19 two FDA letters, and they are the old ones. So, I have no  
20 way of evaluating the significance or the language of any  
21 subsequent letters. We have the -- all along we were given  
22 the August 15, 2006, warning letter and the revised warning  
23 letter of February 1st, 2007. Those are the only ones we've  
24 ever seen.

25 Now, let me hear from the defense.

1 MR. MORIARTY: Two points, Your Honor.

2 First of all, I think all, but certainly the vast  
3 majority of the depositions that we're here about today,  
4 were taken before the ruling on PTO 52. So, we did not have  
5 that guidance to judge these depositions.

6 A lot of these depositions were in October/November or  
7 January/February, and I don't remember when PTO 52 came out,  
8 but I don't think it was until late February or sometime in  
9 March. So, -- but we have the ability, as we did the first  
10 time, to identify what products were made right before and  
11 right after Digitek.

12 We also have the ability to identify all the products  
13 that were made on a Stokes BB2 tablet press such as the ones  
14 that manufactured Digitek batch 70924. I think that's less  
15 than 10 products. It might be less than eight products that  
16 are made on the Stokes BB2's. So, there is a way to contain  
17 the universe to reasonably related consistent with PTO 27  
18 and still stick with the same presses.

19 But I guess I would thoroughly agree with you that  
20 liquids and capsules and some of these other things are, are  
21 wholly irrelevant and outside what we should be doing here.  
22 There is a way to get to tablet, tablets that are even  
23 close.

24 THE COURT: If, if there's a breakdown in quality  
25 in people even caring if they're doing their job right and

1 the quality assurance people deciding to go out and drink  
2 beer rather than to actually run the lab tests, then of  
3 course gelcaps, liquids, tablets are all equally susceptible  
4 to being adulterated and potentially lethal, or at least  
5 damaging.

6 MR. MORIARTY: And, Your Honor, I don't --

7 THE COURT: And because of that, I'm inclined to  
8 think that it is appropriate for the plaintiffs to have  
9 leave to inquire into the functioning of that quality  
10 assurance department.

11 Mr. Galea was brought in to harmonize it, to bring it  
12 up to, to par, whatever words he wanted to use. But the  
13 judicial officers always know a whole lot less about the  
14 case than the lawyers do. And it's extremely hard for me to  
15 be able to formulate a ruling that somehow manages to, to do  
16 this efficiently and economically while still ensuring that  
17 the plaintiffs have the opportunity to investigate their  
18 case.

19 MR. MORIARTY: And, Your Honor, --

20 THE COURT: I mean -- and let me say that the FDA  
21 established that your clients were not doing a good job.  
22 And plaintiffs' attorneys as one of their functions shined  
23 bright lights on corporate entities who were not doing their  
24 job the right way. So, -- but let's not waste a whole lot  
25 of money and let's not go far afield.

1                   MR. MORIARTY: And, and I think, Your Honor, for  
2 the most part we have let the witnesses answer those general  
3 questions. But when they start to go toward specific  
4 products other than Digitek, that's where we've kind of  
5 drawn the line. And I think the number of objections where  
6 we've actually stopped them is not as big as some may, may  
7 claim. But we will find out.

8                   But still in the scope of a litigation like this, and  
9 we can get to ultimate theories and what we're going to be  
10 talking about in October and in motions, the mere fact that  
11 my client has a general warning letter or a 483 about a  
12 particular topic that is very general is not proof regarding  
13 this product that we are here about.

14                 Ultimately the inquiry -- and this is not necessarily  
15 an issue for discovery, but ultimately the issue is going to  
16 be whether my client manufactured defective Digitek that  
17 made its way to their clients.

18                 THE COURT: Right.

19                 MR. MORIARTY: And they need all this cGMP  
20 questions because they have no evidence of defective  
21 Digitek. So, in the end there's going to be a lot of  
22 general discovery done that's all in the 483s and warning  
23 letters already that they have. I guess that's all I can  
24 say about that. But there are ways to limit this inquiry.

25                 THE COURT: Mr. Thompson.

1                   MR. THOMPSON: Judge, I noticed that -- I, I guess  
2 I was taken aback at the torrent of documents in this case  
3 that -- I was taken aback that, that, your statement that  
4 you had not had the 483 from the May, March through May  
5 inspection put into the court record. We've used it so much  
6 in deposition that I, I guess I assumed that it was papered  
7 on the walls on billboards. But we did make reference to it  
8 in our memorandum.

9                   I certainly -- if that was -- if it was anything that  
10 was important to the Court, I would, I would create a  
11 supplemental exhibit and, and serve it and, and, and file  
12 it.

13                  But what it contains is a series of observations of  
14 quality deviations, some of which do include Digitek and  
15 some of which include other solid pills, some of which  
16 include training, some of which include quality problems,  
17 lab problems. We believe that we should be able to inquire  
18 into those observations.

19                  One of the fascinating aspects of this discovery  
20 depositions is that the Actavis deponents to a person  
21 testified that they were running a very, very good shop.  
22 And when you juxtapose that with the FDA findings, you find  
23 a degree of obliviousness that is really kind of shocking.

24                  And, and certainly Mr. Moriarty points out our burden,  
25 and there are several ways to, to reach that burden, one of

1 which is to show a departure from good manufacturing  
2 practice which constitutes an adulterated product as a  
3 matter of law. And we certainly are going to pursue that as  
4 well as the, the general departure from specs that, that we  
5 see.

6 But with regard to where we go from here, I think that  
7 my suggestion is a, is a workable one and it doesn't require  
8 us to push the rock back up the hill, that it allows us to  
9 go forward and get the information that we need to, to meet  
10 the Court's scheduling order.

11 THE COURT: Well, and that would be that the  
12 plaintiffs have leave to retake such depositions as they  
13 choose with respect to quality assurance.

14 MR. THOMPSON: Yes, Your Honor, quality  
15 department.

16 THE COURT: Quality department. I understand that  
17 there's kind of an umbrella organization that has several  
18 sections.

19 MR. MORIARTY: I just have one last thing to say.

20 THE COURT: Yes, Mr. Moriarty.

21 MR. MORIARTY: The plaintiffs constantly trumpet  
22 this shutdown. We need to be very precise. The FDA did not  
23 shut down Actavis at any point.

24 The Actavis -- or the FDA never said that the company  
25 could not produce Digitek if it wanted to. And the events

1   that happened in May or June of 2008 was a voluntary recall,  
2   not to the consumer level, and the FDA did not enjoin the  
3   company from continuing to produce products if it wished,  
4   didn't shut the plant down. It didn't seize products.

5           And the fact that it wasn't a recall to the consumer  
6   level is significant because this whole GMP issue that the  
7   plaintiffs want to use to make their indirect proof of  
8   defect wasn't to the level of public safety that the FDA was  
9   so concerned about that they urged my client to make those  
10   all-other-product recalls to the consumer level. It's very  
11   significant.

12          So, as we continue to go through this case, those will,  
13   that will come out and be flushed out in more detail. But  
14   they tend to paint that all-products recall as the FDA  
15   coming in and putting their boot on my client's throat,  
16   which is not the case.

17           THE COURT: Well, I'm going to go on vacation.  
18   And, so, I am not going to be available to field phone calls  
19   from depositions during April 16th through the 30th. And I  
20   am wondering to what extent the parties anticipate that  
21   you're going to get into a disagreement as to which  
22   questions may be answered.

23           MR. THOMPSON: Judge, I'm told that the next  
24   scheduled deposition we have is April the 30th who is the  
25   former president, W. Patel. So, that will not arise in real

1 time for a week and a half or so.

2 You know, Judge, as spirited as we have been on our two  
3 sides, we have always had an opportunity to, to work  
4 together, and we've always done that pretty successfully.

5 It may not appear that way from the bench, but this is  
6 actually one of the most collegial MDLs that I've ever been  
7 in. We've done more by agreement than any other MDL that  
8 I've been associated with.

9 And I, for one, would -- having had the benefit of your  
10 direction, I would, I would at least give it a try to, to go  
11 forward and, and, and have your direction impressed on both  
12 of us and expect us both to, to follow it.

13 THE COURT: All right. Well, I'll be back on the  
14 3rd. I -- the defense raised this big issue as to whether  
15 the plaintiffs were seeking reconsideration of Pre-Trial  
16 Orders 27 and 37, and then went into a discussion of Rule 59  
17 which utterly does not relate to interlocutory orders.

18 And I -- is there any need for me to address whether  
19 Pre-Trial Order 27 has any, has been changed? I want to  
20 make sure that I'm not creating more discovery disputes down  
21 the road. Maybe you're far enough along that I can just  
22 leave it as is.

23 If there's any question about it, I think the parties  
24 should assume that I believe the plaintiffs are entitled to  
25 inquire about current good manufacturing practices, where

1      Digitek was manufactured, particularly with respect to  
2      personnel, training, housekeeping, testing, quality control.  
3      It's a waste of time for you to spend a whole lot of time  
4      asking about a bunch of questions that are irrelevant. And  
5      I think you-all are good lawyers and don't want to waste  
6      your time. So, I think you'll figure it out. I hope I  
7      don't have to re-address this.

8                    MR. THOMPSON: Judge Stanley, let me ask one  
9      question. If -- I haven't talked with Mr. Moriarty about  
10     this, but if we were to inquire as to whether or not a  
11     private court reporter might transcribe this proceeding in  
12     order to assist the Court, that may not be an option, but I  
13     do believe it would be helpful as we go forward in the  
14     absence of a written order to have access to the transcript  
15     and to have so that -- I'm the worst paraphraser in the  
16     world, and I could very easily hear you any way I, it's to  
17     my advantage to hear you. So, it might be of real benefit  
18     to have a transcript of this.

19                   THE COURT: We are going to enter an order. I  
20     think that we, we'll be able to get this recording  
21     transcribed in relatively short order, perhaps within a week  
22     or so. And if you want it expedited, of course there's an  
23     extra charge for that.

24                   MR. THOMPSON: No, Judge, I -- I had probably a  
25     neurotic thought that I was being helpful to the Court.

1 But --

2 THE COURT: I think as we go through the various  
3 resources we've got -- my concern is that I think they're  
4 doing daily copy in the death penalty case. So, that really  
5 sucks up the manpower.

6 MR. THOMPSON: Thank you, Your Honor.

7 THE COURT: Okay. Thank you-all.

## 8 (Proceedings concluded)

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13 I, Lisa A. Cook, Official Reporter of the United  
14 States District Court for the Southern District of West  
15 Virginia, do hereby certify that the foregoing is a true and  
16 correct transcript, to the best of my ability, from the  
17 record of proceedings in the above-entitled matter.

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21 Reporter

April 16, 2010

21 Reporter

Date

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